



K032704 1 of 2
Innovatech SURGICAL, INC.

OCT 24 2003

August 26, 2003

Premarket Notification [510(k)] Summary

Submitter: Innovatech Surgical Inc.
1000 Atlantic Avenue, Suite 514
Camden, NJ 08104
Phone: 800-240-3123
Fax: 856-225-1203

Official Correspondent: Michael J. McGowan, Sr.

Trade Name: Innovatech Illuminating Laser Probe

Common Name: Ophthalmic Laser Probe

Registration Number: 3003988504

Classification: Class II

Class Name: We were unable to find the device listed in the Disposable classification regulations, 21 CFR Parts 862-892 [807.87 (c)]

Panel: Ophthalmic

Product Code: HQF

Device Description: The Innovatech Illuminating Laser Probe is an ophthalmic laser delivery device. By its design, it does not generate, intensify or significantly reduce energy. It consists of a connector that is plugged into an existing laser source, a glass fiber for laser delivery and acrylic fiber for illumination with PVC jacket, a Delrin handpiece and 304 stainless needle. The specific laser source to which the probe is connected will be specified in the "Indications for Use."

Statement of Indications for use: For photocoagulation during ophthalmic surgery. To be used with (specified equipment).

Substantial Equivalence Comparison

Application for 510(k)	Substantial Equivalence to:		
Innovatech Illuminating Laser Probe Product: 420-30	Peregrine Illuminated Laser Probe Product: PD600.10 Manufactured by Peregrine Surgical Ltd 510(k): K031023	HGM Illuminating Laser Probe (Gamp & Associates) 510(k): K931784	Peregrine Straight Laser Probe Product: PD600.00 Manufactured by Peregrine Surgical Ltd 510(k): K024061
Illumination and Light transmission for photocoagulation	Illumination and Light transmission for photocoagulation	Illumination and Light transmission for photocoagulation	Light transmission for photocoagulation
Aluminum connector	Aluminum connector	Aluminum connector	Aluminum connector
Delrin Handpiece	Delrin Handpiece	Delrin Handpiece	Delrin Handpiece
Optical Fiber Glass – Silica Core .008" (200 microns)	Optical Fiber Glass – Silica Core .008" (200 microns)	Optical Fiber Glass – Silica Core .008" (200 microns)	Optical Fiber Glass – Silica Core .008" (200 microns)
PVC Jacket	PVC Jacket	Teflon Jacket	PVC Jacket
Length 101 inches	Length 101 inches	Length 96 inches	Length 101 inches
304 Stainless Needle	304 Stainless Needle	304 Stainless Needle	304 Stainless Needle
20 Gauge	20 Gauge	20 Gauge	20 Gauge
Max power output 1 watt	Max power output 1 watt	Max power output 1 watt	Max power output 1 watt
Illumination	Illumination	Illumination	No illumination
Acrylic Optical fiber	Acrylic Optical fiber	Acrylic Optical fiber	N/A

Sterility

The Device will be ETO Sterilized.

The method used to validate the sterilization cycle is AAMI Overkill Method.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2003

Mr. Michael J. McGowan, Sr.
Innovatech Surgical, Inc.
1000 Atlantic Avenue, Suite 514
Camden, New Jersey 08104

Re: K032704

Trade/Device Name: Innovatech Illuminating Laser Probe
Regulation Number: 21 CFR 878.4810, 886.4390
Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology, Ophthalmic laser
Regulatory Class: II
Product Code: GEX, HQF
Dated: August 26, 2003
Received: September 2, 2003

Dear Mr. McGowan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Michael J. McGowan, Sr.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K032704

Device Name: Innovatech Illuminating Laser Probe

Indications for Use: For photocoagulation and illumination during ophthalmic surgery. This device delivers illumination, as well as laser energy, to target tissue causing coagulation. Spot size can be varied by altering the distance between the tissue and the probe tip.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED:

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use xx OR Over-The-Counter Use

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032704